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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,297	06/23/2003	Jacob Stoltze	S63.2-11064-US01	3241
490 7590 12/11/2007 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER EREZO, DARWIN P	
			ART UNIT 3773	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/603,297

Applicant(s)

STOLTZE ET AL.

Examiner

Darwin P. Erez

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3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,8-14,16,17 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,8-14,16,17 and 19-27 is/are rejected.
- 7) ☒ Claim(s) 26 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/1/07 has been entered.

Claim Objections

2. Claims 26 and 27 are objected to because of the following informalities:
3. Claim 26 recites the limitation "stent member" while the independent claim uses the limitation "stent". Claim 26 should recite "...wherein the stent is expandable and capable of permanent deformation when expanded."
4. Claim 27 is dependent upon a cancelled claim. When treating the claim on the merit, it will be viewed as being dependent upon claim 14.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim recites "the matrix material comprising a non-elastomeric material". However, there is no teaching in the specification, or in any incorporate reference of the matrix material itself being non-elastomeric. This claim was previously rejected under 35 USC 112, first paragraph in the Office action mailed on 8/18/06. The applicant argued that there is support for this limitation in claim 10 of WO 95/33422. However, upon further review, this argument is not persuasive. Claim 10 of WO 95/33422 recites "wherein said catheter member is formed from a non-elastomeric thermoplastic material". Claim 12 of WO 95/33422 further discloses that the "non-elastomeric material is enclosed with an elastomeric material". Thus, the "non-elastomeric material" actually refers to the "fibers", while the "elastomeric material" refers to the "matrix". As such, there is no teaching of the matrix itself as being comprised of non-elastomeric material. In fact, it is the fiber itself, which is also part of the catheter member, that is made of non-elastomeric material.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5, 9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by UK Patent No. 1,455,674 (will be referred to as the UK patent).

(claim 1) The UK patent discloses a balloon catheter comprising fibers (reinforcement fabric) that are embedded in a matrix material, wherein the fibers are non-elastomeric. The applicant clearly admits of this reinforced balloon in page 11, lines 25-34 of the specification.

(claims 2-3) The fibers are viewed as reinforcement fibers for controlling expansion of the balloons.

(claim 5) The fibers are braided or wound in a helical shape (page 2, lines 112-120).

(claim 9) The UK patent discloses the matrix to made of polyvinyl chloride, which is a known thermoplastic (page 1, line 46).

(claim 13) The balloon is part of a balloon catheter.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over UK Patent No. 1,455,674 (will be referred to as the UK patent), and in further view of US 5,201,706 to Noguchi et al.

The UK patent discloses all the limitations of the claims except for the fiber being formed of thermoplastic materials, such as polyethylene. However, Noguchi also discloses a reinforced balloon having reinforcement fibers, wherein the fiber can be high-tenacity polyethylene (col. 4, line 2). It is noted that the fiber of the UK patent and the fiber of Noguchi are art-recognized equivalents because they are both used to reinforce an inflatable portion of a balloon catheter. Therefore, since these two materials are well known equivalents in the art at the time the invention was made, one of ordinary skill in the art would have found it obvious to use one known material for the other known material.

12. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over UK Patent No. 1,455,674 (will be referred to as the UK patent), and in further view of US 4,706,670 to Anderson et al.

The UK patent discloses all the limitations of the claims except for the matrix being formed from a polyurethane elastomer. However, Anderson also discloses a reinforced balloon, wherein the balloon comprises a reinforced fiber embedded in a polyurethane coating matrix (col. 5, lines 48-56). It is noted that the polyvinyl chloride matrix of the UK patent and the polyurethane matrix of Anderson are art-recognized equivalents since both provide elastomeric characteristic to the inflatable portion of the balloon. Therefore, since these two materials are well known equivalents in the art at

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the time the invention was made, one of ordinary skill in the art would have found it obvious to use one known material for the other known material.

13. Claims 14, 16, 17, 19, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over UK Patent No. 1,455,674 (will be referred to as the UK patent), and in view of US 5,100,429 to Sinofsky.

(claims 14, 26 and 27) The UK patent discloses an catheter having an inflatable portion, as recited in the rejection to claim 1 above, but is silent with regards to the balloon catheter being used in combination with a stent. However, the use of a balloon catheter for expanding a stent is well known in the art. For instance, Sinofsky discloses a stent **112** releasably attached or mounted by a bond (col. 9, lines 51-53) to an inflatable portion of a catheter **120**, wherein the stent is capable of retaining a deployed configuration. Therefore, it would have been obvious to one of ordinary skill in the art to use a stent with the inflatable balloon of the UK patent because the reinforced inflatable balloon of the UK patent would allow the use of high-pressure within the balloon to fully inflate the balloon without rupturing said balloon.

(claims 16 and 17) See the rejections to claims 2 and 3 above.

(claims 19) See the rejection to claim 5 above.

14. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over UK Patent No. 1,455,674 (will be referred to as the UK patent), and in view Sinofsky, and in further view of Noguchi et al., as applied to the rejections to claims 6 and 8 above.

The UK patent discloses all the limitations of the claims except for the fiber being formed of thermoplastic materials, such as polyethylene. However, Noguchi also discloses a reinforced balloon having reinforcement fibers, wherein the fiber can be high-tenacity polyethylene (col. 4, line 2). It is noted that the fiber of the UK patent and the fiber of Noguchi are art-recognized equivalents because they are both used to reinforce an inflatable portion of a balloon catheter. Therefore, since these two materials are well known equivalents in the art at the time the invention was made, one of ordinary skill in the art would have found it obvious to use one known material for the other known material.

15. Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over UK Patent No. 1,455,674 (will be referred to as the UK patent), and in view Sinofsky, and in further view of Anderson et al., as applied to the rejections to claims 10 and 11 above.

The UK patent discloses all the limitations of the claims, including a non-elastomeric material (fiber) enclosed within an elastomeric material (matrix), but is silent with regards to the elastomeric material being formed from a polyurethane elastomer. However, Anderson also discloses a reinforced balloon, wherein the balloon comprises a reinforced fiber embedded in a polyurethane coating matrix (col. 5, lines 48-56). It is noted that the polyvinyl chloride matrix of the UK patent and the polyurethane matrix of Anderson are art-recognized equivalents since both provide elastomeric characteristic to the inflatable portion of the balloon. Therefore, since these two materials are well known equivalents in the art at the time the invention was made, one of ordinary skill in

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the art would have found it obvious to use one known material for the other known material.

Response to Arguments

16. Applicant's arguments with respect to claims 1-3, 5, 6, 8-14, 16, 17 and 19-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/
Examiner
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